641—4.4(136A) Expanded maternal serum alpha-fetoprotein screening program. This program provides comprehensive second trimester maternal screening services for the state.

4.4(1) *Maternal screening policy.* It shall be the policy of the state of Iowa that all pregnant women are offered the Iowa expanded maternal serum alpha-fetoprotein (MSAFP)/Quad Screen. The Iowa expanded MSAFP/Quad Screen measures the maternal serum levels of alpha-fetoprotein, unconjugated estriol, human chorionic gonadotropin, and inhibin-A to provide a risk assessment for open neural tube defects, ventral wall defects, Down syndrome, Trisomy 18, and Smith-Lemli-Opitz. If a patient desires this screening test, the specimen shall be drawn and submitted by her health care provider to the University Hygienic Laboratory, the center's designated central laboratory.

4.4(2) *Maternal screening procedure.*

a. Collection of specimens. A serum or clotted blood specimen shall be collected from the patient during 15 to 20 weeks of gestation.

b. Processing of specimens. The central laboratory shall test specimens within three working days of receipt.

c. Reporting of abnormal results. Abnormal test results shall be reported within 24 hours to the consulting physician or the physician's designee who shall then notify the submitting health care provider. On the next working day, this initial report shall be followed by a written report to the submitting health care provider.

4.4(3) *Consulting physician responsibility.* A consulting physician shall be designated by the center in collaboration with the central laboratory to provide interpretation of test results and consultation to the submitting health care provider. This physician shall provide consultation for abnormal test results, assist with questions about management of identified cases, provide education and assist with quality assurance measures. The screening program with assistance from the consulting physician shall:

a. In collaboration with the central laboratory, submit a proposed budget and narrative justification for the upcoming fiscal year to the center by January 31 of each year, and

b. Submit a written annual report of the previous fiscal year to the center by September 30 of each year. The report shall include:

(1) Number of women screened,
(2) Number of repeat screens,
(3) Number of abnormal results by disorder,
(4) Number of rejected specimens,
(5) Results of quality assurance testing, and
(6) Screening and educational activity details.

4.4(4) *Central laboratory responsibility.* The central laboratory shall:

a. Test specimens within three working days of receipt.

b. Distribute specimen collection kits and other materials to health care provider offices and drawing facilities as required.

c. Inform the submitting health care provider or drawing facility of an unacceptable specimen and request another specimen.

d. Provide educational materials concerning specimen collection procedures.

e. Have available for review a written quality assurance program covering all aspects of its screening activity.

f. Act as a fiscal agent for program charges encompassing the analytical, technical, administrative, educational and follow-up costs for the screening program.

4.4(5) *Iowa expanded MSAFP/Quad Screen fee determination.* The department shall annually review and determine the fee to be charged for all activities associated with the MSAFP/Quad Screen. The review and determination of the fee shall be completed at least one month prior to the beginning of the fiscal year.

4.4(6) *Sharing of information and confidentiality.* Reports, records, and other information collected by or provided to the Iowa expanded MSAFP/Quad screening program relating to a patient's maternal serum screening results and follow-up information are confidential records pursuant to Iowa Code section 22.7.

a. Personnel of the program shall maintain the confidentiality of all information and records used in the review and analysis of maternal serum screening and follow-up, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. The program shall not release confidential information except to the following persons and entities, under the following conditions:

(1) The patient for whom the report is made.

(2) A local health care provider, or submitting laboratory.

(3) A representative of a state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency will be subject to confidentiality regulations which are the same as or more stringent than those in the state of Iowa.

(4) A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department and the state board of health.

4.4(7) *Retention, use and disposition of residual maternal serum screening specimens.*

a. A maternal serum screening specimen collection consists of laboratory tubes with maternal serum screening specimens and attached information about the patient, health care provider, or drawing laboratory.

(1) Maternal serum screening specimens shall be held for a specified period of time in a locked area at the central laboratory in accordance with central laboratory policy and procedures.

(2) Reserved.

b. Research use.

(1) Investigators shall submit to the center proposals to use maternal serum screening specimens. Any intent to utilize information associated with the residual maternal serum screening specimen for the research study must be clearly delineated in the proposal.

(2) Before research can commence, proposals shall be approved by the researcher's institutional review board, the congenital and inherited disorders advisory committee, and the department.

(3) Personally identifiable residual specimens or records shall not be disclosed without documentation of informed patient consent obtained by the researcher.

(4) Research on anonymized or identifiable residual specimens shall be allowed in instances where research would further maternal serum screening activities or general medical knowledge for existing public health surveillance activities.